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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/493,484	01/28/2000	Adriaan Anthonius Wilhelmus Marie Van Loon	1999.454 US	2307

7590 10/22/2002

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PATENT DEPARTMENT
405 STATE STREET
MILLSBORO, DE 19966

EXAMINER

PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 10/22/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/493,484

Applicant(s)

VAN LOON, ADRIAAN
ANTHONIUS WILHELMUS M

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 10-13 and 15 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14 is/are allowed.
- 6) ☒ Claim(s) 5-9 and 16-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Response to Amendment

Status of the Claims

1. Acknowledgement is hereby made of receipt and entry of the response filed 16 August, 2002, wherein claim 14 was amended and new claims 16-25 submitted. Claims 5-9, 14, and 16-25 are currently under examination while claims 1-4, 10-13, and 15 stand withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

35 U.S.C. § 112, Second Paragraph

2. The previous rejection of claims 5-9 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is hereby withdrawn in response to applicant's arguments.

35 U.S.C. § 112, First Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The previous rejection of claims 5-9 and 14 under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure for the claimed invention, is hereby withdrawn in response to the Declaration provided by W. P. Ramey, III.

5. Claims 5-9 and 16-25 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in

the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In *re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). In *re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). The claims are directed toward vaccine compositions comprising a large genus of avian reoviruses that are capable of inducing antiserum that displays different degrees of inhibition (e.g., 75%, 80%, or 90%) as determined by a plaque reduction assay. Other identifying criteria include negative limitations specifying that the avian reovirus of interest does not react with a series of monoclonal antibodies.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Vas-Cath, Inc., v. Mahurkar*, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116. The issue raised in this application is whether the original application provides adequate support for the broadly claimed genus of avian reoviruses that are present in the vaccine composition. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by functional characteristic, without any known or disclosed correlation between that function

and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the biomolecule of interest. *In re Bell*, 991 F.2d 781, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1993). *In re Deuel*, 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995). A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1995). The court noted in this decision that a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not reasonably lead those skilled in the art to any particular species.

An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. For some biomolecules, examples of identifying characteristics include a nucleotide or amino acid sequence, chemical structure, binding affinity, binding specificity, and molecular weight. The written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. Without such a correlation, the capability to recognize or understand the structure from the mere

recitation of function and minimal structure is highly unlikely. In the latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement. *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 U.S.P.Q.2d 1398, 1404, 1406 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). *In re Wilder*, 736 F.2d 1516, 1521, 222 U.S.P.Q. 369, 372-3 (Fed. Cir. 1984). Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.

The disclosure fails to provide adequate guidance pertaining to a number of these factors as follows:

1) The disclosure fails to provide the complete nucleotide or amino acid sequence of any given avian reovirus. While it is noted that the disclosure describes the isolation and preliminary characterization of a single avian reovirus (designated ERS) bearing the E.C.A.C.C. accession no. 9901475, this is the only virus that was isolated in the specification. Nucleotide and amino acid sequence data was not provided for this isolate or any other isolate.

2) The only properties used to describe the claimed invention are directed toward their ability to induce antiserum in an animal that produces a certain degree plaque reduction when measured in an art-recognized plaque reduction assay. Another defining property is directed toward a negative limitation that simply specifies that the avian reovirus of interest does not react with a small group of monoclonal antibodies of undefined specificity. These simple defining criteria are insufficient to distinguish one avian reovirus from another.

3) The disclosure fails to provide any structural correlation toward the functional properties being measured. For instance, the claimed genus is being defined by their ability to induce antisera with a certain neutralizing activity. However, the disclosure fails to provide any correlation between the induction of said antisera and corresponding genotypic/phenotypic changes in the reoviral genome. Thus, the skilled artisan cannot readily ascertain if they are in possession of the claimed invention.

4) The disclosure fails to provide a reproducible method for making a homogenous population of avian reoviruses with similar structures and functions. The avian reovirus of interest was isolated from chickens having digestive problems and passaged on a suitable cell lines. The ability of this virus to induce neutralizing antisera was assessed using a plaque reduction assay. However, this assay fails to provide any guidance pertaining to the molecular determinants that modulate the desired phenotype of the virus. It has been well-documented that the avian reoviruses display considerable genotypic/phenotypic heterogeneity (Nersessian et al., 1989; Rosenberger et al., 1989; Patrick et al., 2001; Jones, 2002; Kapczynski et al., 2002). Thus, using the described methodology, the skilled artisan can only guess as to what the final product will be.

When all the aforementioned factors are considered in toto, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention. The skilled artisan would only conclude that applicants were in possession of a single avian reovirus having the E.C.A.C.C. accession no. 9901475. Appropriately drafted claim language directed toward this embodiment would be acceptable.

Allowable Subject Matter

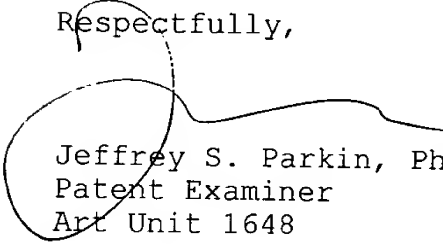
6. Claim 14 appears to be free of the prior art and is allowable.

Correspondence

5 7. Correspondence related to this application may be submitted to
Group 1600 by facsimile transmission. The faxing of such papers
must conform with the notice published in the Official Gazette,
1096 OG 30 (November 15, 1989). Official communications should be
directed toward one of the following Group 1600 fax numbers: (703)
308-4242 or (703) 305-3014. Informal communications may be
submitted directly to the Examiner through the following fax
number: (703) 308-4426. Applicants are encouraged to notify the
10 Examiner prior to the submission of such documents to facilitate
their expeditious processing and entry.

15 8. Any inquiry concerning this communication should be directed to
Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227.
The examiner can normally be reached Monday through Thursday from
8:30 AM to 6:00 PM. A message may be left on the examiner's voice
mail service. If attempts to reach the examiner are unsuccessful,
the examiner's supervisors, James Housel or Laurie Scheiner, can be
reached at (703) 308-4027 or (703) 308-1122, respectively. Any
20 inquiry of a general nature or relating to the status of this
application should be directed to the Group 1600 receptionist whose
telephone number is (703) 308-0196.

Respectfully,


Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

19 October, 2002